



MANUFACTURER'S DECLARATION OF CONFORMITY

This is a declaration made in accordance with the requirements of Medical Device Regulation (MDR) 2017/745 relating to Eakin products manufactured by Pelican Healthcare Limited. This declaration is issued under the sole responsibility of TG Eakin Ltd.

Manufacturer's Name: TG Eakin Ltd

Business Address: 15 Ballystockart Road, Comber, Co. Down,
BT23 5QY, Northern Ireland

Medical Device(s): See attached list

Risk Class: Class I in accordance with MDR Annex VIII

Basic UDI-DI (GMN): 5017710000012T – General Ostomy
5017710000022V – Urostomy

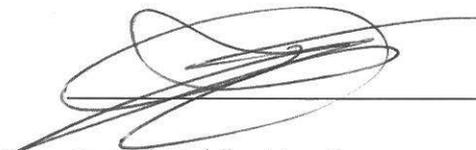
Statement of Compliance: I hereby confirm that the device(s) covered by this declaration are in conformity with the stated regulation.

Scope of Application: This certificate is valid for all products identified in the attached list for an undetermined period of time.

Common specifications used: None

Single Registration number (SRN): XI-MF-000006712

Authorised Signatory:

 '02 August 2021.

Janet Fairlie-Vogt
Interim Director, International Ostomy and Wound
Date of issue:
Place of issue: Comber, Co. Down

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Controlled Listings for CE - Marked Products (Eakin products manufactured by Pelican Healthcare Limited)

Declaration of Conformity: TGE019

Product Reference No.	Product description	UDI-DI
839312	Pelican Drainable Maxi Clear CTF	15065663004873
839336	Pelican Drainable Std Clear CTF	15065663004736
839337	Pelican Drainable Std Clear 20mm	15065663004743
839338	Pelican Drainable Std Clear 25mm	15065663004750
839339	Pelican Drainable Std Clear 27.5mm	15065663004767
839340	Pelican Drainable Std Clear 30mm	15065663004774
839341	Pelican Drainable Std Clear 32.5mm	15065663004781
839342	Pelican Drainable Std Clear 35mm	15065663004798
839343	Pelican Drainable Std Clear 37.5mm	15065663004804
839344	Pelican Drainable Std Clear 40mm	15065663004811
839345	Pelican Drainable Std Clear 45mm	15065663004828
839346	Pelican Drainable Std Clear 50mm	15065663004835
839360	Pelican Drainable Mini Clear CTF	15065663004859
839401	Pelican Closed Maxi Clear CTF	15017710000628
839414	Pelican Closed Std Clear CTF	15017710000758
839415	Pelican Closed Std Clear 22.5mm	15017710000765
839416	Pelican Closed Std Clear 25mm	15017710000772
839417	Pelican Closed Std Clear 27.5mm	15017710000789
839418	Pelican Closed Std Clear 30mm	15017710000796
839419	Pelican Closed Std Clear 32.5mm	15017710000802
839420	Pelican Closed Std Clear 35mm	15017710000819
839421	Pelican Closed Std Clear 37.5mm	15017710000826
839422	Pelican Closed Std Clear 40mm	15017710000833
839423	Pelican Closed Std Clear 45mm	15017710000840
839424	Pelican Closed Std Clear 50mm	15017710000857
839425	Pelican Closed Std Clear 55mm	15017710000864
839438	Pelican Closed Mini Clear CTF	15017710000994
839489	Convex Drainable Maxi Clear CTF	15017710001106
839500	Convex Drainable Std Clear CTF	15065663004415
839501	Convex Drainable Std Clear 20mm	15065663004422
839502	Convex Drainable Std Clear 22.5mm	15017710001212
839503	Convex Drainable Std Clear 25mm	15065663004439
839504	Convex Drainable Std Clear 27.5mm	15065663004446
839505	Convex Drainable Std Clear 30mm	15065663004453
839506	Convex Drainable Std Clear 32.5mm	15017710001229
839507	Convex Drainable Std Clear 35mm	15065663004460
839508	Convex Drainable Std Clear 37.5mm	15017710001236



839509	Convex Drainable Std Clear 40mm	15017710001243
839511	Convex Drainable Mini Clear CTF	15017710001267
839512	Convex Drainable Std Clear CTF up to 60mm	15017710001922
839512NF	Convex Drainable Std Clear CTF up to 60mm (no fabric)	15017710011884
839520	Adjustable Belt for Pelican Pouches up to 100cm	15017710001663
839530	Convex Closed Std Clear CTF	15065663004408
839531	Convex Closed Std Clear 20mm	15017710001274
839532	Convex Closed Std Clear 22.5mm	15017710001281
839533	Convex Closed Std Clear 25mm	15017710001298
839534	Convex Closed Std Clear 27.5mm	15017710001304
839535	Convex Closed Std Clear 30mm	15017710001311
839536	Convex Closed Std Clear 32.5mm	15017710001328
839537	Convex Closed Std Clear 35mm	15017710001335
839538	Convex Closed Std Clear 37.5mm	15017710001342
839539	Convex Closed Std Clear 40mm	15017710001359
839540	Convex Urostomy Std Clear CTF	15065663004477
839541	Convex Urostomy Std Clear 20mm	15065663004514
839542	Convex Urostomy Std Clear 22.5mm	15017710001366
839543	Convex Urostomy Std Clear 25mm	15065663004521
839544	Convex Urostomy Std Clear 27.5mm	15065663004538
839545	Convex Urostomy Std Clear 30mm	15065663004545
839546	Convex Urostomy Std Clear 32.5mm	15017710001373
839547	Convex Urostomy Std Clear 35mm	15065663004552
839548	Convex Urostomy Std Clear 37.5mm	15017710001380
839549	Convex Urostomy Std Clear 40mm	15017710001397
839550	Convex Urostomy Maxi Clear CTF	15017710001403
839551	Convex Urostomy Mini Clear CTF	15017710001410
839562	Convex Closed Maxi Clear CTF	15017710001526
839574	Convex Closed Std Clear CTF up to 60mm	15017710001915
839575	Convex Urostomy Std Clear CTF up to 60mm	15017710001908
839576	Convex Closed Mini Clear CTF	15017710006712
839580	Pelican Stoma Cap CTF	15017710001649
839581	Pelican Stoma Cap Plus CTF	15017710001656
839602	Pelican Urostomy Maxi Clear CTF	15065663004590
839603	Pelican Urostomy Std Clear CTF	15065663004606
839604	Pelican Urostomy Std Clear 20mm	15065663004613
839605	Pelican Urostomy Std Clear 25mm	15065663004620
839606	Pelican Urostomy Std Clear 27.5mm	15065663004637
839607	Pelican Urostomy Std Clear 30mm	15065663004644
839608	Pelican Urostomy Std Clear 32.5mm	15065663004651
839609	Pelican Urostomy Std Clear 35mm	15065663004668



839610	Pelican Urostomy Std Clear 37.5mm	15065663004675
839611	Pelican Urostomy Std Clear 40mm	15065663004682
839612	Pelican Urostomy Std Clear 45mm	15065663004699
839615	Pelican Urostomy Mini Clear CTF	15065663004729
839701	Paediatric Clear (Printed) CTF	15065663004385
839703	Neonatal Clear (Printed) CTF	15065663004569
839706	Paediatric Urostomy Clear (Printed) CTF	15065663004392
839707	Paediatric Clear Convex Drainable Printed CTF	15017710002288
839708	Paediatric Clear Convex Urostomy Printed CTF	15017710006422

And any of the above product codes prefixed by SP which denotes samples of the same item which are identical to the items listed above.

And any of the above product codes prefixed by a 2-letter country code (e.g. FR, DE, JP) which denotes a country-specific variant of the same item, which is identical to the item listed above, differing in labelling language, UDI and/or pack size only